SPECIFIC PROVISIONS FOR THE ACCREDITATION OF CERTIFICATION BODIES IN THE FIELD OF MEDICAL DEVICE QUALITY MANAGEMENT SYSTEMS (ISO 13485)

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DOCUMENT HISTORY

Revision and date of approval	Reason for revision	Impact of revision
0 **CC 22.01.2015**	New document - Formal integration of IAF MD 8:2015 and MD 9:2015 in the management system documentation of BELAC	
0 **Secr.** **18.05.2018**	Revision of IAF MD 8:2017 and IAF MD 9:2017 Revision of ISO 17021-1:2015 Revision of ISO 17011:2017	Full document

SPECIFIC PROVISIONS FOR THE ACCREDITATION OF CERTIFICATION BODIES IN THE FIELD OF MEDICAL DEVICE QUALITY MANAGEMENT SYSTEMS (ISO 13485)

1. OBJECTIVES AND REFERENCES TO NORMATIVE DOCUMENTS

This document is intended to document the specific requirements and guidelines that shall apply for the accreditation of certification bodies in the field of medical device quality management systems (ISO 13485) or as part of the conformity assessment activities of bodies notified in the framework of the relevant European harmonized Legislation.

It includes in particular :

- The specific requirements and guidelines related to the organization and operation of the certification body;
- The specific requirements and guidelines applicable to BELAC.

The specific requirements and guidelines for the direct performance of the conformity assessment activities are not detailed in the present document but a reference to the relevant documents is included.

The specific requirements and guidelines

- are only endorsed when they comply with the general criteria documented in BELAC document 1-03 ;
- complement the requirements and guidelines that are in force to all BELAC accreditation activities.

2. RECIPIENTS

With follow up of modifications:

- Members of the Coordination Commission
- Members of the Accreditation Board
- Accreditation secretariat
- Assessors and experts
- Accredited bodies

Without follow up of the modifications: Any external request

3. DESCRIPTION OF THE ACTIVITY

3.1 Identification of the activity	**MDQS**
3.2 Type(s) of conformity assessment and accreditation standard	Certification of quality management system according to ISO 13485 • Accreditation according to EN ISO 17021-1:2015
3.3 Classification(s) according to BELAC 6-017	7.8
3.4 Reference document(s) for the activity ***(hereafter named "the scheme")*** , including the publication date or a version number	• ISO 13485:2003 (until 01/03/2019) - ISO 13485:2016 • ISO 14971:2007 • IAF MD 8:2017 (Application of ISO/IEC 17011) • IAF MD 9:2017 (Application of ISO/IEC 17021) • IMDRF (International Medical Device Regulatory Forum) / relevant documents GHTF Study Group 3 – Quality systems and GHTF Study Group 4 – Auditing) www.iaf.nu www.imdrf.org
3.5 Body responsible for the development and maintenance of the scheme ***(hereafter named « the scheme owner »)***	ISO EU (in case of certification within the framework of the relevant European Directives

4. SPECIFIC REQUIREMENTS APPLICABLE TO THE CONFORMITY ASSESSMENT BODY

During the accreditation assessments according to EN ISO/IEC 17021-1:2015 for certification against ISO 13485 or for conformity assessment activities provided by bodies notified in the framework of the relevant European harmonized Legislation, a specific evaluation is required to establish the compliance with the specific requirements listed hereafter; the relevant information will be included in the assessment report.

EN ISO 17021-1:2015	Specific requirement of IAF MD 9:2015
Clause 4.4 **Responsibility**	**MD.4.4.1** ISO 13485 requires the organization to comply with the statutory and regulatory requirements applicable to the safety and performance of the medical devices. The maintenance and evaluation of legal compliance is the responsibility of the client organization. The CAB is responsible for verifying that the client organization has evaluated statutory and regulatory compliance and can show that appropriate action has been taken in cases of non-compliance with relevant legislation and regulations, including the notification to the Regulatory Authority of any incidences that require reporting.
Clause 4.5 **Openness**	**MD.4.5.1** In order to increase the confidence from interested parties and specifically regulators that accept or take into consideration ISO 13485 accredited certification for the purpose of their recognitions, it is expected that CABs establish appropriate agreements with their clients to release audit report information to regulators that recognize ISO 13485.
Clause 5.2 **Management of impartiality**	**MD 5.2.3** The CAB and its auditors shall be impartial and free from engagements and influences which could affect their objectivity, and in particular shall not be: a) involved in the design, manufacture, construction, marketing, installation, servicing or supply of the medical device, or any associated parts and services b) involved in the design, construction, implementation or maintenance of the quality management system being audited c) an authorized representative of the client organization, nor represent the parties engaged in these activities. The situations hereafter are examples where impartiality is compromised in reference to the criteria defined in a) to c): i) the auditor having a financial interest in the client organization being audited (e.g. holding stock in the organization) ii) the auditor being employed currently by a manufacturer producing medical devices iii) the auditor being a member of staff from a research or

	medical institute or a consultant having a commercial contract or equivalent interest with the manufacturer or manufacturers of similar medical devices.
Clause 7.1 **Competence of management and personnel**	**MD 7.1.1 Management and personnel competence** Where ISO/IEC 17021-1 Clause 7.1.1 refers to (as relevant for the specific certification scheme) ISO 13485, this should be understood to mean medical devices and applicable legal requirements. All management and personnel involved in ISO 13485 certification shall meet the competency requirements of Annex B.
Clause 7.2 **Personnel involved in the certification scheme**	**MD 7.2.1 Auditor** Each auditor shall have demonstrated competency as defined in Annex C. The CAB shall identify authorizations of its auditors/technical experts using the Technical Areas in Tables in Annex A. **MD 7.2.4 Auditor experience** For a first authorization, the auditor shall comply with the following criteria, which shall be demonstrated in audits under guidance and supervision: a) have gained experience in the entire process of auditing medical devices' quality management system, including review of documentation and risk management of applicable medical devices, parts or services (see Table A.1.7), implementation audit and audit reporting. This experience shall have been gained by participation as a trainee in a minimum of four audits for a total of at least 20 days in an accredited QMS program, 50% of which shall be against ISO 13485 preferably in an accredited program, and the rest in any other accredited QMS program. In addition to criteria a), audit team leaders shall fulfil the following: b) have experienced an audit team leader role under the supervision of a qualified team leader at least three ISO 13485 audits. **MD 7.2.8 Personnel making the certification decision** The CAB shall ensure that personnel (group or individual) making the certification decision fulfill the competence in Annex B. This does not mean that each individual in the group needs to comply with all requirements, but the group as a whole shall meet all the requirements. When the certification decision is made by an individual, the individual shall meet all the requirements.
Clause 8.1 **Public information)**	**MD 8.1.3** Where it is required by law or by the relevant Regulatory Authority, the CAB shall provide the information about certifications granted, suspended or withdrawn to relevant Regulatory Authority.

Clause 8.2 **Certification documents**	**MD 8.2.1** The CAB shall precisely document the scope of certification. The CAB shall not exclude part of processes, products or services (unless allowed by regulatory authorities) from the scope of certification when those processes, products or services have an influence on the safety and quality of products.
Clause 9.1 **Pre-certification activities)**	**MD 9.1.2.1** If the applicant organization uses outsourced processes, the CAB shall determine and document whether specific competence in the audit team is necessary to evaluate the control of the outsourced process. **MD 9.1.4 Determining audit time** The requirements from IAF Mandatory document MD5 (Duration of QMS and EMS Audit) apply except those for EMS and the table QMS 1. The Annex D, table D.1 replaces table QMS 1 and provides a starting point for estimating the duration of an initial audit (Stage 1 + Stage 2) for ISO 13485 certification. Audit duration is dependent on factors such as the audit scope, objectives and specific regulatory requirements to be audited, as well on the range, class and complexity of medical devices, and the size and complexity of the organization. When CABs are planning audits, sufficient time shall be allowed for the audit team to determine the conformity status of the client organization's quality management system with respect to the relevant regulatory requirements. Any additional time required to audit national or regional regulatory requirements and dossier reviews must be justified. Audit duration for all types of audits includes on site time at a client's premises and time spent off-site carrying out planning, document review, interacting with client personnel and report writing. It does not consider the time required for design dossier reviews, type examinations, pre-market approval audits and other similar activities. The audit duration should be adjusted to take into account the factors listed in Annex D which may increase or decrease the estimated audit time. For those CAB's offering both ISO 9001 and ISO 13485 certification to a client, the audit time shall be able to demonstrate sufficient time to conduct an effective review to determine conformity with all requirements of both certification standards. For integrated audits see IAF MD11 **MD 9.1.5 Multi-site sampling** Sites involved in design, development and manufacturing of medical devices (Table A.1.1-1.6) cannot be sampled.

Clause 9.2 **Planning audits**	**MD 9.2.2.1** The audit team shall have the competence for the Technical Area (Annex A in conjunction with relevant knowledge and skills as defined in Annex B) for the scope of audit. If the audit is performed for an organization that only parts and services (see Table A.1.7), the audit team does not have to demonstrate technical competence at the same level as that for a manufacturer producing medical devices. To include devices that are sterile or intended for end-user sterilization, the audit team shall be competent according to sterilization process detailed in Table 1.5 of Annex A.
Clause 9.3 **Initial certification**	**MD 9.3.1** When a certification body has audited a client against a regulatory scheme that includes or goes beyond the requirements of ISO 13485, it does not need to repeat the audit for conformity with the elements of ISO 13485 previously covered, providing the CAB can demonstrate that all of the requirements of this document have been complied with. Note: Typical regulatory schemes that include or go beyond the requirements of ISO13485 are European Medical Device Directives and Regulations: i) Medical Device Regulation (MDR) ii) In-Vitro Diagnostic Devices Directive (IVD) iii) Active Implantable Medical Devices Directive (AIMD) Other jurisdictions include: i) Canada – Health Canada, Canadian Medical Devices Conformity Assessment System (CMDCAS) ii) Australia – Therapeutic Goods Administration, Therapeutic Goods Regulations Additionally other countries are adopting or considering adopting ISO 13485 into their Medical Device Regulations. **MD 9.3.1.2 Stage 1**Where higher risk medical devices (e.g. GHTF C and D) are concerned, the stage 1 audit should be performed on-site.
Clause 9.4 **Conducting audits**	**MD 9.4.5 Identifying and recording audit findings** Examples of nonconformities are as follows: i) failure to address applicable requirements for quality management systems (e.g. failure to have a complaint handling or training system) ii) failure to implement applicable requirements for quality management systems iii) failure to implement appropriate corrective and preventative action when an investigation of post market data indicates a pattern of product defects iv) products which are put onto the market and cause undue risk to patient and/or users when the device is used according to the product labelling v) the existence of products which clearly do not comply with the client's specifications and/or the regulatory requirements vi) repeated nonconformities from previous audits

Clause 9.6 **Maintaining certification**	**MD 9.6.2.2** In addition to requirements of Clause 9.6.2.2, the surveillance program shall include a review of actions taken for notification of adverse events, advisory notices, and recalls. **MD 9.6.4.2** Short notice or unannounced audits may be required when: i) external factors apply such as: a) available post-market surveillance data known to the CAB on the subject devices indicate a possible significant deficiency in the quality management system b) significant safety related information becoming known to the CAB ii) significant changes occur which have been submitted as required by the regulations or become known to the CAB, and which could affect the decision on the client's state of compliance with the regulatory requirements. The following are examples of such changes which could be significant and relevant to the CAB when considering that a special audit is required, although none of these changes should automatically trigger a special audit: i) <u>QMS – impact and changes</u>: a. New ownership b. Extension to manufacturing and/or design control c. New facility, site change • Modification of the site operation involved in the manufacturing activity (e.g. relocation of the manufacturing operation to a new site or centralizing the design and/or development functions for several manufacturing sites) d. new processes, process changes • Significant modifications to special processes (e.g. change in production from sterilization through a supplier to an on site facility or a change in the method of sterilization) e. QM management, personnel • Modifications to the defined authority of the management representative that impact: o quality management system effectiveness or regulatory compliance o the capability and authority to assure that only safe and effective medical devices are released ii) <u>Product related changes</u>: a. New products, categories b. Addition of a new device category to the manufacturing scope within the quality management

	system (e.g. addition of sterile single use dialysis sets to an existing scope limited to haemodialysis equipment, or the addition of magnetic resonance imaging to an existing scope limited to ultrasound equipment) c) QMS & Product related changes: a. Changes in standards, regulations b. Post market surveillance, vigilance An unannounced or short-notice audit may also be necessary if the CAB has justifiable concerns about implementation of corrective actions or compliance with standard and regulatory requirements.

5. SPECIFIC REQUIREMENTS APPLICABLE TO BELAC

The following table includes the specific requirements of IAF MD 8:2017 not explicitly covered by the general BELAC provisions for the accreditation of management systems certification bodies.

ISO/IEC 17011:2004 / ISO/IEC 17011:2017 and/or ref to BELAC documents	**IAF MD 8:2017**	**Specific requirements**
Clause 6.2 Personnel involved in the accreditation process BELAC 3-05 BELAC 3-09 BELAC 2-405-MDQS	MD 6.2.1	Normative Annex E specifies the type of knowledge and skills that the Accreditation Body shall define for specific functions.
Clause 7.5/7.4 Preparation for assessment **BELAC 3-11**	MD 7.5.6	In the case of initial assessment, the samples for witnessing of audits shall include an audit of the higher risk class of the technical areas (shown in Annex 1) covered under the scope of accreditation. When developing a witnessing schedule, the Accreditation Body should consider, among other factors, the experience of the CAB e.g. recognized for one or more medical device regulatory scheme(s), in an effort to rationalize the witnessing schedule. Typical regulatory schemes are European Medical Devices Directives and Regulations: i. Medical Device Regulation (MDR) ii. In -Vitro Diagnostic Devices Directive (IVD) iii. Active Implantable Medical Devices Directive (AIMD) Other jurisdictions include: i. Canada – Health Canada, Canadian Medical Devices Conformity Assessment System (CMDCAS) ii. Australia – Therapeutic Goods Administration, Therapeutic Goods Regulations
Clause 7.9 Decision-making and granting accreditation / 7.7 Accreditation decision-making + 7.8 Accreditation information BELAC 3-11	MD 7.9.5 + Appendix 1	The accreditation certificate shall indicate the scope of accreditation which should clearly specify the Technical Areas as defined in Annex A – Scope of Accreditation.

Clause 7.11 Reassessment and surveillance / Clause 7.9 Accreditation cycle BELAC 3-11	MD 7.11.2	The surveillance on-site office assessments shall be conducted at least once a year. Surveillance and reassessment shall include on-site assessment as well as witnessing. The witnessing program shall ensure, as a minimum, that one audit from each of the Main Technical Areas (shown in Annex A) under the scope of accreditation within an accreditation cycle (surveillances and/or reassessment) is conducted prior to the expiry of accreditation. The sampling for witnessing shall give priority to higher risk technical areas. Witness assessments should avoid the repeated witnessing of the same CAB client organization. The AB shall take into account previous results of witnessing to establish its witness strategy. All premises where one or more key activities are performed shall be assessed during the accreditation cycle.

5.1. Regulatory Competent authorities:

In case of certification against ISO 13485 in the framework of the activities as notified body for Directive 93/42 modified by Directive 2007/47:

AFMPS	Agence fédérale pour les médicaments et les produits de santé
FAGG	Federaal agentschap voor geneesmiddelen en gezondheidsproducten
FAMHP	Federal Agency for Medicines and Health Products

Annex A:
(Normative)
Medical Devices Technical Areas

Accreditation scope	**Certification scope**
When using technical areas other than specified below as scope of accreditation, the technical areas shall be detailed. Main Technical Areas in Table 1.1 – 1.6 are applicable to finished medical devices. Note: A finished medical device is defined as any device or accessory to any medical device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized. Where the CAB is seeking accreditation for a scope, which includes non-manufacturing activities or manufacturing of parts which are not categorized as finished medical devices, Table 1.7 shall be used for scoping. Any other product that does not have medical or therapeutic purposes (border line products such as cosmetic, herbal, nutritional supplements, beauty equipment etc.) or not directly connected to the prevention or restoration of the health state of the persons cannot be classified as a medical device. To this end, the choice of provider to fall into the classification of the medical device must be supported by a decision of the regulatory authority.	The CAB shall use the technical Areas described in the tables of this Annex i) To help define the scope of certification ii) To identify if any technical qualification, including competence in sterilization processes of its auditors is necessary for that particular technical area iii) To select a suitable qualified audit team When using technical areas other than specified in the tables, the technical areas shall be detailed. Main Technical Areas in Table A.1.1 – 1.6 are applicable to finished medical devices. Note: A finished medical device is defined as any device or accessory to any medical device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized. Where the organization provides associated activities or manufacturing of parts which are not categorized as finished medical devices, Table A.1.7 shall be used for scoping. Any other product that does not have medical or therapeutic purposes (border line products such as cosmetic, herbal, nutritional supplements, beauty equipment, etc.) or not directly connected to the prevention or restoration of the health state of the persons cannot be classified as a medical device. To this end, the choice of provider to fall into the classification of the medical device must be supported by a decision of the regulatory authority and indicated in official Guidelines or Specifications issued to that purpose..

Table A.1.1 - NON-ACTIVE MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Non-active medical devices	General non-active, non-implantable medical devices	• Non-active devices for anesthesia, emergency and intensive care • Non-active devices for injection, infusion, transfusion and dialysis • Non-active orthopedic and rehabilitation devices • Non-active medical devices with measuring function • Non-active ophthalmologic devices • Non-active instruments • Contraceptive medical devices • Non-active medical devices for disinfecting, cleaning, rinsing • Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) • Non-active medical devices for ingestion
	Non-active implants	• Non-active cardiovascular implants • Non-active orthopedic implants • Non-active functional implants • Non-active soft tissue implants
	Devices for wound care	• Bandages and wound dressings • Suture material and clamps • Other medical devices for wound • care
	Non-active dental devices and accessories	• Non-active dental • devices/equipment and instruments • Dental materials • Dental implants
	Non-active medical devices other than specified above	

Table A.1.2 - ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES

Main Technical Areas	**Technical Areas**	**Product Categories Covered by the Technical Areas**
Active Medical Devices (non implantable)	General active medical devices	• Devices for extra-corporal circulation, infusion and haemopheresis • Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia • Devices for stimulation or inhibition • Active surgical devices • Active ophthalmologic devices • Active dental devices • Active devices for disinfection and sterilisation • Active rehabilitation devices and active prostheses • Active devices for patient positioning and transport • Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) • Software • Medical gas supply systems and parts thereof
	Devices for imaging	• Devices utilizing ionizing rays • Devices utilizing non-ionizing rays
	Monitoring devices	• Monitoring devices of non-vital physiological parameters • Monitoring devices of vital physiological parameters
	Devices for radiation therapy and termotherapy	• Devices utilising ionizing radiation • Devices utilising non-ionizing radiation • Devices for hyperthermia /hypothermia • Devices for (extracorporal) shockwave therapy (lithotripsy)
	Active (non-implantable) medical devices other than specified above	

Table A.1.3 - ACTIVE IMPLANTABLE MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Active implantable Medical Devices	General active implantable medical devices	• Active implantable medical devices • for stimulation / inhibition • Active implantable medical devices delivering drugs or other substances • Active implantable medical devices substituting or replacing organ functions
	Implantable medical devices other than specified above	

Table A.1.4 - IN VITRO DIAGNOSTIC MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
In Vitro Diagnostic Medical Devices (IVD)	Reagents and reagent products, calibrators and control materials for: • Clinical Chemistry • Immunochemistry (Immunology) • Haematology/Haemostasis/Immunohema-tology • Microbiology • Infectious Immunology • Histology/Cytology • Genetic Testing	
	In Vitro Diagnostic Instruments and software	
	IVD Medical devices other than specified above	

Table A.1.5 – STERILIZATION METHODS FOR MEDICAL DEVICES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Sterilization Method for Medical Devices	Ethylene oxide gas sterilization (EOG)	
	Moist heat	
	Aseptic processing	
	Radiation sterilization (e.g gamma, x-ray, electron beam)	
	Sterilization method other than specified above	

Table A.1.6 – DEVICES INCORPORATING / UTILIZING SPECIFIC SUBSTANCES /TECHNOLOGIES

Main Technical Areas	Technical Areas	Product Categories Covered by the Technical Areas
Devices incorporating/ utilizing specific substances / technologies	Medical devices incorporating medicinal substances	
	Medical devices utilizing tissues of animal origin	
	Medical devices incorporating derivates of human blood	
	Medical devices utilizing micromechanics	
	Medical devices utilizing nanomaterials	
	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed	
	Medical devices incorporating or utilizing specific substances/technologies/elements other than specified above	

Table A.1.7 – PARTS AND SERVICES

Main Technical Areas	**Technical Areas**	**Product Categories Covered by the Technical Areas**
Parts or services	Raw materials	Raw metals, plastic, wood, ceramic
	Components	Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic
	Subassemblies	Electronic subassemblies mechanical subassemblies, made to drawings and/or work instructions
	Calibration services*	Verification/confirmation services for measuring instruments, tools or test fixtures
	Distribution services	Distributors providing storage and delivery of medical devices, not acting as a 'legal manufacturer' for medical devices.
	Maintenance services	Electrical or mechanical repair services, facility cleaning and maintenance services, uniform cleaning and testing of ESD smocks.
	Transportation services	Trucking, shipping, air transportation service in general.
	Other services	Consulting services related to medical devices, packaging services, etc.

*Organizations providing calibration services should be accredited to ISO/IEC 17025

Annex B.
(Normative)
Required types of knowledge and skills for personnel involved with the ISO 13485 activities

The following table specifies the type of knowledge and skills that a CAB shall define for specific functions in addition to ISO/IEC 17021-1 Annex A.

Table B.1 – Table of knowledge and skills

Certification functions / Knowledge and skills	Personnel conducting the application review to determine audit team competence required, to select the audit team members, and to determine the audit duration	Personnel reviewing audit reports and making certification decisions	Auditor	Personnel managing program
Knowledge of generic quality management system practices	x	x	x	x
Knowledge of legal framework of regulations and role of the CAB	x	x	x	x
Knowledge of medical device risk management, e.g. ISO 14971	x	x	x	x
Knowledge of intended use of medical devices			x*	
Knowledge of risks associated with the medical device			x*	
Knowledge of relevant product standards in the assessment of medical devices			x*	
Knowledge of CAB's ISO 13485 processes	x	x	x	x
Knowledge of Medical Device business/technology	x	x	x*	x

* The knowledge in the areas marked with * could be provided by a technical expert

Annex C
(Normative)
Auditor qualification, training and experience

C.1 Education

The CAB shall ensure that auditors have the knowledge corresponding to post-secondary education or equivalent work experience. Appropriate professional areas are listed below as examples:

i) biology or microbiology;
ii) chemistry or biochemistry;
iii) computer and software technology;
iv) electrical, electronic, mechanical or bioengineering;
v) human physiology;
vi) medicine;
vii) pharmacy;
viii) physics or biophysics.

C.2 Work Experience

The CAB shall ensure that auditors have adequate experience to perform their tasks.
In general, auditors shall have a minimum of four years of full-time work experience in the field of medical devices or related sectors (e.g. industry, healthcare, audit or research in medical devices or related area).

Successful completion of other formal qualification (advanced degrees) can substitute for a maximum of two years of working experience.

Exceptionally, shorter duration of experience or experience in the fields other than medical devices or related sectors may be considered as appropriate. In such cases, the CAB shall demonstrate that the experience of the auditor is equivalent and shall record the justification for the acceptance.

C.3 Auditor Competency

See Annex B.

C.4 Development and maintenance of competency

C.4.1 Continuous Professional Development (CPD)

Each auditor shall undertake CPD activities such as training, participation in scientific meetings, and self-study.
Such activities should ensure timely awareness of new or modified regulatory requirements, policies, procedures, etc., as well as emerging technologies. Training in emerging technologies may be provided through co-operation with manufacturers developing or using the concepts. Knowledge is also gained from experience in enforcing regulatory requirements, implementing procedures, and applying policies and interpretations.

It is recognised that medical device manufacturing constitutes a highly specialized, technology driven and fast evolving sector. Additionally, new regulatory requirements,

standards, policies, and procedures are introduced, and existing ones are modified from time to time. Therefore, the CAB shall ensure maintenance of the knowledge and skills of the auditors appropriate to cover the scope of audits of organizations, through appropriate and timely training and encouraging CPD.

C.4.2 Advanced training elements for auditors

As auditors gain competence in conducting audits, advanced and specialised training is recommended. The auditor's needs, weaknesses, and desires for career development may influence specific advanced training courses selected by an auditor. Subjects suggested for advanced training include:

i) Risk management, including risk analysis;
ii) Process validation;
iii) Sterilization and related processes;
iv) Electronics manufacture;
v) Plastics manufacturing processes;
vi) Development and validation of software or hardware for devices and manufacturing processes;
vii) In-depth knowledge of specific medical devices and/or technologies.

Annex D
(Normative)
Relationship between effective number of personnel and audit duration
(Initial Audit only)

Effective number of personnel	Audit duration Stage 1 + Stage 2 (days)	Effective number of personnel	Audit duration Stage 1 + Stage 2 (days)
1-5	3	**626-875**	15
6-10	4	**876-1175**	16
11-15	4,5	**1176-1550**	17
16-25	5	**1551-2025**	18
26-45	6	**2026-2675**	19
46-65	7	**2676-3450**	20
66-85	8	**3451-4350**	21
86-125	10	**4351-5450**	22
126-175	11	**5451-6800**	23
176-275	12	**6801-8500**	24
276-425	13	**8501-10700**	25
426-625	14	**>10700**	Follow progression above

Factors used to determine the audit time:

i) Some factors that may increase the audit duration are
   a. Number of ranges and/or complexity of medical devices.
   b. Manufacturers using suppliers to supply processes or parts that are critical to the function of the medical device and/or the safety of the user or finished products, including own label products. When the manufacturer cannot provide sufficient evidence for conformity with audit criteria, then additional time may be allowed for each supplier to be audited.
   c. Manufacturers who install product on customer's premises.
      Note: Time may be required for customer site visits or installation records review
   d. Poor regulatory compliance by the manufacturer
   e. Multiple shifts, number of production lines etc. may increase audit duration

ii) Some factors that may reduce the audit duration but not by more than 20 % in total are
   a. The organization's scope does not include manufacturing and is activities such as wholesale, retail, transportation or maintenance of equipment etc.
   b. Reduction of the manufacturer product range since last audit
   c. Reduction of the design/or production process since last audit

iii) Audit durations performed solely for the certification scope of Distribution or transportation Services" may be reduced up to 50% in total from table D.1.

_ANNEX 2
(Normative)
Required types of knowledge and skills for personnel involved with the IAF ISO 13485 activities

The following table specifies the type of knowledge and skills that AB shall define for specific functions.

Accreditation functions / Knowledge and skills	Application review	Document review	Office assessment team	Witness assessment team	Reviewing assessment reports and making accreditation decisions	Administering program
Principles and applications of quality systems.		X	X	X	X	
Understanding of applicable GHTF SG4 and SG3 documents. (Being maintained by IMDRF)			X	X		
Understanding of ISO 13485			X	X	X (Note 1)	
Understanding of general regulatory requirements relevant to medical device manufacturers.			X	X	X (Note 1)	
Overview of medical devices, their intended use, safety and risks.			X	X		
The legal framework, including the regulatory requirements, their enforcement, and the role of the auditing organization.			X	X		
Information on CAB's client products, processes and organization to determine competence needed by the audit team and for the certification decision			X			
Information on CAB's processes and organization to determine competence needed by the assessment team and for the accreditation decision						X

Understanding CAB's client's products, processes and organization				X		
Ability to confirm that the CAB's processes are appropriate to support IAF ISO 13485 scheme.		X	X	X		
Ability to confirm that the CAB is competent to conduct a certification of the manufacturers, taking into account the processes and products involved.			X	X	X	
Ability to determine required appropriate duration of assessment.						X
Identification of medical devices including complexities, technologies, intended use and risk classifications.			X	X		
Deployment of assessor competences and requirements.						X
Knowledge on identifying and evaluating factors that impact an appropriate certification program for a medical device manufacturer seeking certification in a regulatory environment.			X	X		
Understanding of work performed at an accredited CAB.		X	X		X	X
Understanding of IAF Mandatory Documents for ISO 13485 scheme	X	X	X	X	X	X
Understanding of ISO/IEC 17021-1		X	X	X	X	X

NOTE 1: It is expected that the level of understanding for this activity would be less than that of an assessment team.